USB Software Media Label Form

The contents of this completed form is used to create the label for physical USB software media. The form is constructed to specify required content.

Use this template when creating labels intended for USB media.

Content of the form includes:

- Field Status: Indication of content which is either required or optional
- Field Description: Indication of field type
- Format: Definition of content and / or structure of expected data
- Actual Data: Specific content required on the media

Use Instructions: Creator (includes but not limited to Product Owner, Engineering, etc):

- Complete all fields.
  - Confer with Marketing representatives, as necessary, for product name, software title and branding information.
  - Confer with Regulatory Affairs (RA) representatives to confirm required regulatory symbols
  - For fields G.1, G.2, G.3 and G.4, these are managed as a set of information; therefore they are either all applicable or all non applicable.

Use Instructions: Recipient (includes but not limited to Supply Chain, Media Manufacturer, etc):

- For each completed data line, use the content of the "actual data" column and place the required text in the specified grid location, as stipulated in the USB media purchase specifications.
  - The far-left edge of the image or text content is to be placed in the specified location.
  - Field locations may be adjusted as necessary to allow for readability and content placement.

Document Revision History

Revision	Date	Author	Change Reference	Reason for Change
1	30 Oct 2018	John Manarik	All Pages	Initial Release
2	25 Apr 2019	B. Roberto	Added detail on format for fields B, E, G.2 and mfg	Added clarity for field formats and added more options for products where Chicago may not be legal manufacturer
3	6 June 2021	B. Roberto	Updated fields A and G1	Clarified character limit and format for product name. Removal of 2D barcode. UDI symbol remains on label Removal of manufacturing. Date field G.3 and renumbering of G fields. Added applicability boxes to UDI, E and G Fields

Field Content

NOTE: All fields have a 32-character limit

Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	GE logo	Not applicable	
A	Required	Device / Product Name	Brand Name™ Product Model 32 Character Limit	Centricity™ Enterprise Archive
B	Required	Part Number and Revision	PPPPPPP- R Format is product specific and may have variable number of digits for the part number "P" or revision "R"	K2042WDED-11
C	Required	Part or Build Number	XXXXXXX XXXXXXX-XXX	REF 2049945-032
D	Required	Device Software Revision	Release with Software Patch or Service Pack (examples 5.7 SP9; 7.0 SP0.0.4.2	4.0 SP23.1
E	Optional	CE Mark	Not applicable	☐ Not Applicable ☒ CE Mark CE ☐ CE 0459 Mark CE 0459 ☐ CE 0197 Mark CE 0197 ☐ CE ____ Mark CE__ Note: NB Number after CE is product specific information so if not 0459 or 0197 needs to be specifically identified in this form
F	Required	Consult Instructions for Use symbol	Not applicable	
Not identified	Optional	UDI symbol	Not applicable	☐ Not Applicable ☒ UDI Symbol precedes the G.1 and G2 UDI numbers:
G.1	Optional	GTIN (GS1 format)	(01)xxxxxxxxxxxxxx 14 digits after (01)	☐ Not Applicable ☒ Applicable GTIN Value: (01)00840682102766 ☐ Applicable, If not GS1 format identify value_____ If not GS1 format – consult with RA regarding content for G.1 and G.2 field

Field ID	Field Status	Field Description	Format	Actual Data
G.2	Optional	UDI Production Identification Number (PIN)	(10)Alpha numeric content	☐ Not Applicable ☒ Applicable UDI PIN: (10)40P2312093659001
Not identified	Required	Manufacturer (specify for legal manufacturer)	Not applicable	☒ GE Healthcare 500 W. Monroe Street., Chicago, IL 60661 USA ☐ ---------- Note: Legal Manufactuer is product specific information so if not GE Healthcare in Chicago, it needs to be specifically identified in this form

Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	GE logo	Not applicable	
A	Required	Device / Product Name	Brand Name™ Product Model 32 Character Limit	Centricity™ PACS Server
B	Required	Part Number and Revision	PPPPPPP- R Format is product specific and may have variable number of digits for the part number "P" or revision "R"	K2042WDED-11
C	Required	Part or Build Number	XXXXXXX XXXXXXX-XXX	REF 2092152-075
D	Required	Device Software Revision	Release with Software Patch or Service Pack (examples 5.7 SP9; 7.0 SP0.0.4.2	6.0 SP10.2.2 LINUX SRVR APPS
E	Optional	CE Mark	Not applicable	☐ Not Applicable ☐ CE Mark ☐ CE 0459 Mark ☒ CE 0197 Mark ☐ CE ____ Mark Note: NB Number after CE is product specific information so if not 0459 or 0197 needs to be specifically identified in this form
F	Required	Consult Instructions for Use symbol	Not applicable	
Not identified	Optional	UDI symbol	Not applicable	☐ Not Applicable ☒ UDI Symbol precedes the G.1 and G2 UDI numbers:
G.1	Optional	GTIN (GS1 format)	(01)xxxxxxxxxxxxxx 14 digits after (01)	☐ Not Applicable ☒ Applicable GTIN Value: (01)00840682104807 ☐ Applicable, If not GS1 format identify value_____ If not GS1 format – consult with RA regarding content for G.1 and G.2 field
G.2	Optional	UDI Production Identification Number (PIN)	(10)Alpha numeric content	☐ Not Applicable ☒ Applicable UDI PIN: (10)60P1022.2094610001D

Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	Manufacturer (specify for legal manufacturer)	Not applicable	☒ GE Healthcare 500 W. Monroe Street., Chicago, IL 60661 USA ☐ ---------- Note: Legal Manufactuer is product specific information so if not GE Healthcare in Chicago, it needs to be specifically identified in this form

Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	GE logo	Not applicable	
A	Required	Device / Product Name	Brand Name™ Product Model 32 Character Limit	Centricity™ Universal Viewer
B	Required	Part Number and Revision	PPPPPPP- R Format is product specific and may have variable number of digits for the part number “P” or revision “R”	K2042WDED-11
C	Required	Part or Build Number	XXXXXXX XXXXXXX-XXX	REF 2088026-993
D	Required	Device Software Revision	Release with Software Patch or Service Pack (examples 5.7 SP9; 7.0 SP0.0.4.2	6.0 SP10.4
E	Optional	CE Mark	Not applicable	☐ Not Applicable ☐ CE Mark ☐ CE 0459 Mark ☒ CE 0197 Mark ☐ CE ____ Mark Note: NB Number after CE is product specific information so if not 0459 or 0197 needs to be specifically identified in this form
F	Required	Consult Instructions for Use symbol	Not applicable	
Not identified	Optional	UDI symbol	Not applicable	☐ Not Applicable ☒ UDI Symbol precedes the G.1 and G2 UDI numbers:
G.1	Optional	GTIN (GS1 format)	(01)xxxxxxxxxxxxxx 14 digits after (01)	☐ Not Applicable ☒ Applicable GTIN Value: (01)00840682103800 ☐ Applicable, If not GS1 format identify value_____ If not GS1 format – consult with RA regarding content for G.1 and G.2 field
G.2	Optional	UDI Production Identification Number (PIN)	(10)Alpha numeric content	☐ Not Applicable ☒ Applicable UDI PIN: (10)60P104.2094097001H

Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	Manufacturer (specify for legal manufacturer)	Not applicable	☒ GE Healthcare 500 W. Monroe Street., Chicago, IL 60661 USA ☐ ---------- Note: Legal Manufactuer is product specific information so if not GE Healthcare in Chicago, it needs to be specifically identified in this form

Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	GE logo	Not applicable	
A	Required	Device / Product Name	Brand Name™ Product Model 32 Character Limit	Centricity™ Universal Viewer Zero Footprint
B	Required	Part Number and Revision	PPPPPPP- R Format is product specific and may have variable number of digits for the part number "P" or revision "R"	K2042WDED-11
C	Required	Part or Build Number	XXXXXXX XXXXXXX-XXX	REF 2089507-130
D	Required	Device Software Revision	Release with Software Patch or Service Pack (examples 5.7 SP9; 7.0 SP0.0.4.2	6.0 SP10.2.2
E	Optional	CE Mark	Not applicable	☐ Not Applicable ☐ CE Mark CE ☐ CE 0459 Mark CE 0459 ☒ CE 0197 Mark CE 0197 ☐ CE ____ Mark CE __ Note: NB Number after CE is product specific information so if not 0459 or 0197 needs to be specifically identified in this form
F	Required	Consult Instructions for Use symbol	Not applicable	
Not identified	Optional	UDI symbol	Not applicable	☐ Not Applicable ☒ UDI Symbol precedes the G.1 and G2 UDI numbers:
G.1	Optional	GTIN (GS1 format)	(01)xxxxxxxxxxxxxx 14 digits after (01)	☐ Not Applicable ☒ Applicable GTIN Value: (01)00840682102988 ☐ Applicable, If not GS1 format identify value_____ If not GS1 format – consult with RA regarding content for G.1 and G.2 field
G.2	Optional	UDI Production Identification Number (PIN)	(10)Alpha numeric content	☐ Not Applicable ☒ Applicable UDI PIN: (10)60P1022.2093796001D

Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	Manufacturer (specify for legal manufacturer)	Not applicable	☒ GE Healthcare 500 W. Monroe Street., Chicago, IL 60661 USA ☐ ---------- Note: Legal Manufactuer is product specific information so if not GE Healthcare in Chicago, it needs to be specifically identified in this form

Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	GE logo	Not applicable	
A	Required	Device / Product Name	Brand Name™ Product Model 32 Character Limit	Centricity™ Universal Viewer Zero Footprint
B	Required	Part Number and Revision	PPPPPPP- R Format is product specific and may have variable number of digits for the part number "P" or revision "R"	K2042WDED-11
C	Required	Part or Build Number	XXXXXXX XXXXXXX-XXX	REF 2089507-143
D	Required	Device Software Revision	Release with Software Patch or Service Pack (examples 5.7 SP9; 7.0 SP0.0.4.2	6.0 SP10.2.2.1
E	Optional	CE Mark	Not applicable	☐ Not Applicable ☐ CE Mark CE ☐ CE 0459 Mark CE 0459 ☒ CE 0197 Mark CE 0197 ☐ CE ____ Mark CE __ Note: NB Number after CE is product specific information so if not 0459 or 0197 needs to be specifically identified in this form
F	Required	Consult Instructions for Use symbol	Not applicable	
Not identified	Optional	UDI symbol	Not applicable	☐ Not Applicable ☒ UDI Symbol precedes the G.1 and G2 UDI numbers:
G.1	Optional	GTIN (GS1 format)	(01)xxxxxxxxxxxxxx 14 digits after (01)	☐ Not Applicable ☒ Applicable GTIN Value: (01)00840682102988 ☐ Applicable, If not GS1 format identify value_____ If not GS1 format – consult with RA regarding content for G.1 and G.2 field
G.2	Optional	UDI Production Identification Number (PIN)	(10)Alpha numeric content	☐ Not Applicable ☒ Applicable UDI PIN: (10)60P102212093796001

Field ID	Field Status	Field Description	Format	Actual Data
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Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	GE logo	Not applicable	
A	Required	Device / Product Name	Brand Name™ Product Model 32 Character Limit	Centricity™ Universal Viewer Zero Footprint
B	Required	Part Number and Revision	PPPPPPP- R Format is product specific and may have variable number of digits for the part number "P" or revision "R"	K2042WDED-11
C	Required	Part or Build Number	XXXXXXX XXXXXXX-XXX	REF 2089507-148
D	Required	Device Software Revision	Release with Software Patch or Service Pack (examples 5.7 SP9; 7.0 SP0.0.4.2	6.0 SP10.2.3
E	Optional	CE Mark	Not applicable	☐ Not Applicable ☐ CE Mark CE ☐ CE 0459 Mark CE 0459 ☒ CE 0197 Mark CE 0197 ☐ CE ____ Mark CE __ Note: NB Number after CE is product specific information so if not 0459 or 0197 needs to be specifically identified in this form
F	Required	Consult Instructions for Use symbol	Not applicable	
Not identified	Optional	UDI symbol	Not applicable	☐ Not Applicable ☒ UDI Symbol precedes the G.1 and G2 UDI numbers:
G.1	Optional	GTIN (GS1 format)	(01)xxxxxxxxxxxxxx 14 digits after (01)	☐ Not Applicable ☒ Applicable GTIN Value:(01)00840682102988 ☐ Applicable, If not GS1 format identify value_____ If not GS1 format – consult with RA regarding content for G.1 and G.2 field
G.2	Optional	UDI Production Identification Number (PIN)	(10)Alpha numeric content	☐ Not Applicable ☒ Applicable UDI PIN:(10)60P10232093796001

Field ID	Field Status	Field Description	Format	Actual Data
Not identified	Required	Manufacturer (specify for legal manufacturer)	Not applicable	☒ GE Healthcare 500 W. Monroe Street., Chicago, IL 60661 USA ☐ ---------- Note: Legal Manufactuer is product specific information so if not GE Healthcare in Chicago, it needs to be specifically identified in this form